UNITED STATES DISTRICT COURT

WESTERN DISTRICT OF LOUISIANA

LAFAYETTE DIVISION

JOHN JEFF LEMELLE

VERSUS

STRYKER ORTHOPAEDICS

CIVIL ACTION NO. 09-0987

JUDGE DOHERTY

MAGISTRATE JUDGE HILL

MEMORANDUM RULING

Pending before this Court is a "Report and Recommendation on Motion to Dismiss" issued by Magistrate Judge Hill, in which the magistrate judge recommends the Motion to Dismiss filed by defendant Stryker Orthopaedics ("Stryker") [Doc. 7] be granted in part and denied in part [Doc. 22]. Specifically, the magistrate judge recommends Stryker's motion be granted with respect to plaintiff's claims alleged under the Louisiana Products Liability Act, and those claims be dismissed, but that the motion to dismiss be denied with respect to plaintiff's redhibition claim. Stryker has filed an objection to the Report and Recommendation [Doc. 23]. For the following reasons, this Court ADOPTS IN PART Magistrate Judge Hill's Recommendations. Specifically, although this Court adopts the magistrate judge's recommendation that plaintiff's state law products liability claims be dismissed, the Court does not adopt the magistrate judge's recommendation that plaintiff's redhibition claim survive, finding that the foregoing redhibition claim is preempted. Therefore, plaintiff's LPLA and redhibition claims are DISMISSED WITH PREJUDICE.

II. Factual and Procedural Background

As set forth in the magistrate judge's Report and Recommendation, plaintiff filed the instant lawsuit on May 12, 2009 in the 27th Judidical District Court for the Parish of St. Landry, Louisiana,

alleging he was damaged as a result of defective hardware manufactured by Stryker which was used in his 2004 right hip replacement surgery. The petitioner alleges on March 3, 2008, his surgeon, Dr. John Cobb, received a letter dated February 28, 2008 from Stryker, stating the Trident Hemispherical Acetabular Shells and Trident PSL Acetabular Shells ("Trident™ System") used in plaintiff's procedure had been recalled. Plaintiff alleges on May 13, 2008, he had to undergo a second surgery to replace the cut and screws in his right hip, which caused him damages.

Plaintiff's Petition totals one and a half pages consisting of five paragraphs. In addition to including the foregoing factual information, plaintiff alleges as follows:

IV.

> The redhibitory vices and defects in the products were peculiarly within the knowledge of the defendant, who manufactured the products but were not disclosed to the petitioner prior to his surgery in 2004. Further, petitioner would not have agreed to the surgery had he known of the defective products.
>
> Therefore, under applicable law, petitioner is entitled to damages for mental pain and suffering as a result of the defective nature in the manufacture of the products, all related expenses, including but not limited to loss [sic] wages, interest thereon, damages for mental anguish, inconvenience, attorney's fees, all other damages that may be proven at the trial of this matter and for all costs of these proceedings.[1]

On June 17, 2009, Stryker removed the case to this Court on the basis of federal diversity jurisdiction. On August 26, 2009, Stryker filed the instant motion to dismiss on grounds plaintiff's state law claims related to the Trident™ System are preempted by federal law. The motion was referred to the magistrate judge, and after full briefing and oral argument, the magistrate judge issued his Report and Recommendation on November 9, 2009 [Doc. 22]. Stryker filed its objections on November 20, 2009 [Doc. 23].

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[1] *See* Plaintiff's Petition, Doc. 1, ¶IV.

2. Legal Analysis

A. Standard of Review

A judge of the court shall make a *de novo* determination of those portions of a magistrate judge's report or specified proposed findings or recommendations to which objection is made. A judge of the court may accept, reject, or modify, in whole or in part, the findings or recommendations made by the magistrate judge. The judge may also receive further evidence or recommit the matter to the magistrate judge with instructions. 28 U.S.C. § 636(b)(1); Local Rule 74.1(B).

B. Standard for Motion to Dismiss

In deciding a Rule 12(b)(6) motion to dismiss, the court "accepts all well-pleaded facts as true, viewing them in the light most favorable to the plaintiff." *Guidry v. American Public Life Ins. Co.*, 512 F.3d 177, 180 (5th Cir. 2007) (citing *In re Katrina Canal Breaches Litig.*, 495 F.3d 191, 205 (5th Cir. 2007), *petition for cert. filed*, (U.S. Nov. 26, 2007) (No. 07-713)). The plaintiff must plead "enough facts to state a claim to relief that is plausible on its face." *Id.*; *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 127 S.Ct. 1955, 1974, 167 L.Ed.2d 929 (2007). "Factual allegations must be enough to raise a right to relief above the speculative level, on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." *Twombly*, 127 S.Ct. at 1965 (citation and footnote omitted).

C. Preemption

The crux of the instant matter is whether plaintiff's redhibition claim is preempted pursuant to the U.S. Supreme Court's decision in *Riegel v. Medtronic*, 552 U.S. 312, 128 S.Ct. 999, 169 L.Ed.2d 892 (2008). *Riegel* held the Medical Device Amendments of 1976, 21 U.S.C. § 360c *et seq.* ("MDA"), to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* ("FDCA"), bars

common law claims challenging the safety and effectiveness of a medical device given pre-market approval ("PMA") by the Food and Drug Administration ("FDA"). In *Riegel,* the plaintiff filed suit after a catheter, classified as a Class III device, used in a medical procedure ruptured. 128 S.Ct. at 1005-06. The plaintiff's suit alleged the device was designed, labeled and manufactured in a manner inconsistent with New York state law. The Supreme Court affirmed the circuit court and district court's dismissal of the action – which consisted of New York common law claims of negligence, strict liability, and implied warranty against the manufacturer – were preempted under the MDA. Based on *Riegel*, Stryker argues, Lemelle's Louisiana law product liability and redhibition claims related to the Trident™ System are preempted.

As the magistrate judge explains in detail in his Report, the FDCA has long required FDA approval for the introduction of new drugs into the market. *Riegel*, 128 S.Ct. at 1002-1003. Until the statutory enactment of the MDA in 1976, the introduction of new medical devices was left largely for the States to supervise as they saw fit. *Id.* (*citing Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475-476, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996)).

With the passage of the MDA, Congress swept back certain state obligations and imposed a regime of detailed federal oversight. Under the MDA, medical devices are classified in three categories, depending on the risks they present to the public. *Gomez v. St. Jude Medical Daig Div. Inc.*, 442 F.3d 919, 929 (5th Cir. 2006). "Devices that present no unreasonable risk of illness or injury are designated Class I and are subject only to minimal regulation by 'general controls.' " *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 476-77, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996) (*citing* 21 U.S.C. § 360c(a)(1)(A)). "Devices that are potentially more harmful are designated Class II" and must comply with a set of regulations coined "special controls." *Lohr*, 518 U.S. at 477, 116 S.Ct.

2240 (*citing* 21 U.S.C. § 360c(a)(1)(B)). Devices that present "a potential unreasonable risk of illness or injury" or which are "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health" are designated Class III. 21 U.S.C. § 360c(a)(1)(C). The Trident™ System at issue in the instant litigation is a Class III medical device, meaning that it had received the highest level of federal oversight provided by the FDA. *See, e.g.*, *Hofts v. Howmedica Osteonics Corporation*, 597 F.Supp.2d 830 (S.D. Ind. 2009); *Covert v. Stryker Corp.*, 2009 WL 2424559 (M.D.N.C. Aug. 5, 2009); *Parker v. Stryker Corp.*, 584 F.Supp.2d 1298, 1300 (D.Colo. 2008).

Before a Class III device may be put on the market, the manufacturer must give the FDA "reasonable assurance" that the device is both safe and effective. *Gomez*, 442 F.3d at 928 (*citing* 21 U.S.C. § 360e(d)(2)). A manufacturer provides "reasonable assurance" through the PMA process. *Id.* The PMA process requires the manufacturer to "submit detailed information regarding the safety and efficacy of their devices, which the FDA then reviews, spending an average of 1,200 hours on each submission." *Id.*, *quoting Lohr*, 518 U.S. at 477, 116 S.Ct. 2240. Significantly, the FDA's involvement with the devices continues even after the PMA is complete. *See, e.g.*, 21 C.F.R. § 814.80 (prohibiting the production or labeling of any device in a manner inconsistent with any conditions of approval specified in the approval order); 21 C.F.R. § 814.3a(d) (requiring an applicant to submit a supplemental application setting forth any proposed changes for FDA approval before implementing any changes).

Congress created two exceptions to the PMA process. First, a grandfather clause permits medical devices marketed before passage of the amendments to remain unless and until the FDA initiates and completes the PMA process. *See Lohr*, 518 U.S. at 478, 116 S.Ct. 2240 (citing 21

U.S.C. § 360e(b)(1)(A); 21 C.F.R. § 814.1(c)(1)). Second, devices that are "substantially equivalent" to a preexisting medical device are exempt from the PMA process and instead subject to a streamlined approval process.[2] *See Lohr*, 518 U.S. at 492-94, 116 S.Ct. 2240 (describing the significant differences between the PMA and the "substantially similar" process under § 510(k)); 21 U.S.C. § 360e(b)(1)(B).

The MDA includes an express preemption provision that states:

> "Except as provided in subsection (b) of this section, *no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement-*
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> "(1) which is *different from, or in addition to*, any requirement applicable under this chapter to the device, and
>
> "(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter."

21 U.S.C. §360k(a) (emphasis added).

The Fifth Circuit has held the PMA process "preempts state tort causes of action to the extent that they relate to safety, effectiveness, or other MDA requirements" if the state law claims impose "substantive requirements" different from, or inconsistent with, the federal law. *Gomez,* 442 F.3d at 929, *citing Martin v. Medtronic, Inc.*, 254 F.3d 573 (5th Cir. 2001). *Martin* involved a Class III medical device (Medtronic's pacemaker) subject to the PMA process. There, the court held the PMA requirements preempted Texas state product-liability tort claims arising from a Class III medical device, including claims of defective design, failure to warn, and inadequate labeling, because those claims related to areas specifically covered in the PMA process and sought to impose requirements that were "different from and, indeed, conflict with" the results of the PMA process.

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[2] This is also known as the "501(k) process," named after the subsection in the original act.

Martin, 254 F.3d at 584.

The Fifth Circuit requires the district court to look through the general duties imposed by the state-law causes of action and consider the effect a successful lawsuit asserting those causes of action would have and determine whether the causes of action threaten the federal PMA process requirements. *Gomez*, 442 F.3d at 930.

D. The Magistrate Judge's Report and Recommendation

In both his opposition brief and at oral argument, plaintiff acknowledged his state law product liability claims are preempted by the MDA. Therefore, in his Report, the magistrate judge recommended dismissal of plaintiff's state law claims brought under the LPLA. That matter has not been objected to, and this Court ADOPTS the magistrate judge's finding as to that aspect of Stryker's motion to dismiss. The foregoing claims are, therefore, DISMISSED WITH PREJUDICE.

However, the plaintiff argued in his brief and at oral argument that his redhibition claim is *not* preempted, because it does not seek to impose different or additional requirements than those imposed by the MDA, but only parallels the federal requirements of the MDA.

The magistrate judge, relying on *Pipitone v. Biomatrix, Inc.*, 288 F.3d 239 (5th Cir. 2002)[3]

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[3] In *Pipitone*, Mr. Pipitone and his wife filed suit alleging causes of action arising under Louisiana tort, products liability, and redhibition laws after Pipitone developed a salmonella infection in his knee following an injection with Synvisc, a Class III device under the MDA. The district court issued several rulings: (1) it granted defendant's motion in limine to exclude the testimony of two witnesses retained by the plaintiff under *Daubert*; (2) it held most of plaintiff's state law claims – including claims for design defect, inadequate warning, and non-comformity with express warning under the LPLA – were preempted by the MDA and, therefore, dismissed with prejudice. However, the district court ruled plaintiff's manufacturing defect and redhibition claims survived preemption. Nevertheless, after holding the redhibition claims were limited to economic loss only, the district court granted summary judgment on those claims in favor of the defendant on grounds that without the testimony of the two experts, the plaintiffs had not presented a genuine issues of material fact tending to show the injection caused the infection.

Notably, **the only issues appealed to the Fifth Circuit were the district court's exclusion of the experts' testimony, the grant of summary judgment on the manufacturing defect and redhibition claims, and the court's ruling that redhibition was limited to economic loss only. Specifically, most of the plaintiffs' state**

and *Hofts v. Howmedica Osteonics Corp.*, 597 F.Supp.2d 830 (S.D. Ind. Feb. 11, 2009), found the plaintiff's redhibition claim is not based on Louisiana requirements that are "different from, or in addition to" the federal requirements of the MDA. Therefore, the magistrate judge concluded plaintiff's redhibition claim is not preempted. In so finding, the magistrate judge concluded the plaintiff has properly and sufficiently pled his redhibition claim under *Twombly*, *supra*, and Rule 8 of the Federal Rules of Civil Procedure.[4]

Stryker objects, arguing the magistrate judge's reasoning is in direct conflict with the Supreme Court's decision in *Riegel*, which specifically held implied warranty claims are preempted; that redhibition is not a "parallel" claim within the meaning of the *Riegel* decision; and that "even if implied warranty claims survived preemption under *Riegel*, the plaintiff's petition wholly fails to sufficiently plead such a claim." This Court now considers Stryker's specific objections within the framework of the applicable law.

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claims for design defect, inadequate warning, and non-conformity with express warning under the LPLA – were dismissed with prejudice as preempted by the MDA. The Fifth Circuit held plaintiffs' manufacturing defect claim and redhibition claim survived preemption, and this holding was not appealed. Therefore, the substantive issue of whether the plaintiffs' redhibition claims survived preemption was not considered on appeal. *See Pipitone*, 288 F.3d at 243 n.4 ("[n]either party takes issue with this holding, and we do not consider it.").

[4] Rule 8 states in pertinent part:

> **(a) Claim for Relief.** A pleading that states a claim for relief must contain:
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> > (1) a short and plain statement of the grounds for the court's jurisdiction, unless the court already has jurisdiction and the claim needs no new jurisdictional support;
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> > **(2)** a short and plain statement of the claim showing that the pleader is entitled to relief; and
> >
> > **(3)** a demand for the relief sought, which may include relief in the alternative or different types of relief.

Fed.R.Civ.P. 8.

E. Analysis

In *Riegel*, the Supreme Court set forth a two-prong analysis for determining whether a plaintiff's state law claims are preempted by the MDA. First, the court must determine whether the federal government has established requirements that are applicable to the device. *See Riegel,* 128 S.Ct. at 1006. If there are federal requirements for the device, then the court must determine whether the plaintiff's state law claim is based on a state requirement with respect to the device that is "different from or in addition to" the federal requirements, and that relates to the safety and effectiveness of the device. *Id.* If the state requirement is different from or in addition to the federal requirements, then such a state requirement is preempted by the MDA.

As a practical matter, any device that has been approved by the PMA process will satisfy the first prong of the *Riegel* preemption analysis, because the PMA process itself establishes federal requirements for a particular device. With respect to the second prong of the analysis, the *Riegel* court equated state common-law duties with state "requirements," and determined that "[a]bsent other indication, reference to a State's 'requirements' includes its common-law duties." *Id.* at 2008. The *Riegel* court held these state "requirements" are preempted when applied to a specific medical device that has undergone the PMA process. *Id.* at 1007-08.

Applying the foregoing analysis to the facts of this case, this Court concludes the federal government has established requirements that are applicable to the Trident™ System at issue, and, therefore, the first prong of the *Riegel* preemption analysis is satisfied. The second prong, addressing whether Louisiana's common law claim of redhibition – commonly referred to as a claim for breach

of implied warranty in other jurisdictions[5] – is based on a state requirement that is "different from or in addition to" federal requirements and that relates to the safety and effectiveness of the device, will be discussed in detail below.

This Court notes the majority of district courts considering the precise issue before this Court – *i.e.*, whether breach of implied warranty claims relating to the specific Trident™ System at issue in this matter are preempted – have concluded they are, indeed, preempted, pursuant to *Riegel*. *See, e.g., Horowitz v. Stryker Corp., et al.*, 613 F.Supp.2d 271 (E.D.N.Y. 2009) (claims for breach of implied warranties of fitness and merchantability preempted by MDA); *Parker v. Stryker Corp., et al.*, 584 F.Supp.2d 1298 (D. Colorado Oct. 22, 2008) (claim for breach of implied warranty of merchantability preempted by MDA); *Covert v. Stryker Corp., et al.*, 2009 WL 2424559 (M.D.N.C. Aug.5, 2009) (accord).[6] Additionally, as the magistrate judge pointed out, the majority of courts considering, generally, whether implied warranty claims in MDA cases that do not involve the Trident™ System are preempted have concluded they are. *See, e.g., In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F.Supp.2d 1147, 1161 (D.Minn.2009) (finding breach of express and implied warranty claims, fraud claims and claims for deceptive trade practices preempted in case involving allegedly defective implantable cardiac defibrillators).

The only case cited by any party in which a claim for breach of implied warranty was

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[5] Under Louisiana law, a claim for breach of implied warranty arises under the redhibition chapter and allows recovery for damage to the product itself and economic loss. *Ivory v. Pfizer, Inc.*, 2009 WL 3230611, at *7 (W.D. La. Sept. 30, 2009); *Dawson Farms, L.L.C. v. BASF Corp., et al*, 2008 WL 5220517, at *2 (W.D.La. Dec. 12, 2008).

[6] Although Stryker includes *Bausch v. Stryker Corp., et al.*, 2008 WL 5157940 (N.D.Ill. Dec. 9, 2008) as support for its argument that virtually all district courts – except the *Hofts* court – have held the claims are preempted, this Court notes the *Bausch* case involves claims of strict liability and negligence, not a claim for breach of implied warranty/redhibition. Therefore, the *Bausch* case is distinguishable.

considered and squarely held *not* to be preempted is *Hofts v. Howmedica Osteonics Corp.*, 597 F.Supp.2d 830 (S.D. Ind Feb. 11, 2009), relied upon by the plaintiff and the magistrate judge. In *Hofts*, which also involved the Trident™ System, the court held plaintiff's Indiana state law claims – including a claim for breach of implied warranty – were not preempted, for the following reasons:

> ... [T]he specific tort claims addressed in *Riegel* were not based on the defendant's alleged failure to follow federal requirements, but instead were based on the plaintiffs' allegations that Medtronic had breached state tort duties even though it had complied with federal requirements. *Riegel*, 128 S.Ct. at 1006, 1011.
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> Here it is clear that Hofts bases his tort claims on his allegations that Howmedica failed to meet the FDA's requirements, not on allegations that Howmedica failed to depart from or exceed those requirements. A jury could find that Howmedica breached the duty of care it owed to Hofts by failing to adhere to the FDA's manufacturing requirements without imposing different or additional requirements. *See Lohr*, 518 U.S. at 495, 116 S.Ct. 2240. Similarly, on Hofts' strict liability claim, a jury could find that Howmedica's deviation from the FDA's manufacturing requirements was unreasonably dangerous without imposing different or additional requirements. If supported by the evidence, these results would be entirely consistent with the legal presumption that the FDA "got it right" in setting those requirements. A jury verdict could simply enforce those same federal requirements. The only state law requirements implicit in Hofts' tort claims are thus identical or parallel to the FDA's federal requirements under *Riegel*, so that Hofts' state tort claims are not preempted under section 360k(a).

Id. at 836-837.

In addition to relying on *Hofts*, as this Court noted previously, the magistrate judge relied on *Pipitone v. Biomatrix*, 288 F.3d 239 (5th Cir. 2002), stating the Fifth Circuit has specifically addressed the issue of preemption of redhibition claims in MDA cases. However, as noted in footnote 4 of this Ruling, the Fifth Circuit did not directly address the issue of preemption in the *Pipitone* case. Thus, this Court has question regarding the magistrate judge's reliance on *Pipitone* when the question at issue – whether claims for redhibition/breach of implied warranty survive preemption in MDA cases – was not squarely decided in that case, and, in fact, was specifically not

even considered by the Court.

Stryker contends the Fifth Circuit *did* squarely address the relevant issue in *Gomez v. St. Jude Medical Daig Division, Inc.*, 442 F.3d 919 (5th Cir. 2006), a case decided four years after *Pipitone* and two years before *Riegel*, and concluded plaintiff's redhibition claim was, indeed, preempted. This Court finds Stryker's argument to be overreaching. Although the summary of the *Gomez* case appearing before the actual opinion indicates plaintiff's "breach of implied warranty" claims were preempted, the Fifth Circuit does not actually address the plaintiff's redhibition claim in any detail in the body of the opinion.[7] In *Gomez*, plaintiff experienced significant narrowing of her arteries following surgery in which a medical device was used to close a hole in her artery wall by means of a collagen plug. Plaintiff filed a products liability action against the manufacturer of the collagen plug. The district court granted the manufacturers' motion for summary judgment based on preemption on all claims – including plaintiff's redhibition claim – except plaintiff's manufacturing defect claims, and then entered judgment as a matter of law in the manufacturers's favor on these manufacturing defect claims. On appeal, the Fifth Circuit, without stating whether it was addressing breach of *implied* or *express* warranty claims, ruled that to permit a jury to decide plaintiff's state law claims that the information, warnings, and training material the FDA required and approved through the PMA process were inadequate under state law "would displace the FDA's exclusive role and expertise in this area and risk imposing inconsistent obligations on [the manufacturer]." 442 F.3d at 931. Therefore, the Fifth Circuit held plaintiff's state law claims for inadequate and incomplete labeling, warning, information, and training were preempted. *Id.* It might be presumed

[7] It is axiomatic that the summary of case, prepared by Westlaw reference attorneys, is not part of the court's opinion.

that this holding encompasses a ruling that the plaintiff's breach of implied warranty claim was preempted, however the opinion does not specifically so state.

In *Gomez*, the Fifth Circuit also addressed plaintiff's argument that it was inappropriate to apply preemption to plaintiff's "warranty claims" to the extent she based them on a later-acquired knowledge theory. The Fifth Circuit disagreed, holding it was appropriate to apply preemption to such claims on the following grounds:

> Medical device manufacturers such as Kendall have ongoing obligations to report experience with the device to the FDA, and the FDA has plenary authority to amend the regulations and requirements it imposed relating to the device, up to and including removing it from the market. At the end of the PMA process leading to approval, the FDA issues conditions of approval requiring the manufacturer to meet ongoing reporting and other obligations. *See* 21 C.F.R. § 814.80; 21 C.F.R. § 814.3a(d). The record shows that after the FDA approved the Angio-Seal, Kendall submitted a proposed change to the warning label recognizing risk for patients with smaller veins, particularly females, and recommending additional procedures to mitigate this risk. Gomez's state-law claims related to Kendall's alleged failure to provide information obtained after the FDA approved the Angio-Seal risk the same interference with the federal regulatory scheme as her other claims and are preempted.

Id. at 931-32.

Thus, in *Gomez*, it is unclear whether the Fifth Circuit specifically addressed plaintiff's breach of implied warranty claims. While the Fifth Circuit discussed plaintiff's "warranty claims," it did so without parsing out whether it was addressing breach of *express* warranty claims or breach of *implied* warranty claims.[8] Notwithstanding the foregoing, it appears the only claims that survived

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[8] Although not binding on this Court, the Court notes the decision authored by Judge Stagg in *McQuiston v. Boston Scientific Corp.*, 2009 WL 4016120 (W.D. La. Nov. 19, 2009), wherein Judge Stagg states "[t]he *Gomez* court did not specifically decide the issue of Louisiana implied warranty claims." Judge Stagg went on to find that, notwithstanding the foregoing,

> the FDA has thoroughly examined the manufacturing process, the safety, and the labeling of every

preemption at the appellate level were plaintiff's manufacturing defect claims. Therefore, to the extent the Fifth Circuit did indeed hold the plaintiff's breach of implied warranty claims were preempted, it appears to have done so without a detailed discussion of same.

After reviewing the arguments of the parties, and considering the apparent lack of a controlling Fifth Circuit opinion squarely addressing the issue, this Court agrees with the finding of Judge Stagg in *Mcquiston*, *supra*, fn. 8. In the instant case, the FDA has thoroughly examined the manufacturing process, safety, and labeling of the Trident™ System. A determination that even though the product complies with the FDA requirements, it has a problem causing it to breach an implied warranty, would impose requirements different from or in addition to those imposed by the FDA. Accordingly, because the FDA approved the Trudent System's labeling and warnings, this Court concludes the plaintiff's breach of implied warranty claim in the instant matter is preempted.

For the sake of completeness of the record, this Court will also address the magistrate judge's finding that the plaintiff sufficiently pled a redhibition claim that could survive preemption. As evidenced by the discussed cases, in cases addressing the issue of preemption under the MDA, the sufficiency of the plaintiff's pleading becomes of critical importance. Indeed, in *Covert v. Stryker Corp.*, 2009 WL 2424559 (M.D.N.C. Aug. 5, 2009),[9] the district court, citing the standard enunciated by the United States Supreme Court in *Twombly*, stated:

> PMA-approved product. A determination that even though the product complies with the FDA requirements, it has a problem causing it to breach an implied warranty, would impose requirements different from or in addition to those imposed by the FDA. Accordingly, because the FDA approved the TAXUS Stent's labeling and warnings, McQuiston's breach of express and implied warranties claims are preempted.

Id. at *6 (internal citations omitted).

[9] Although this court is not bound by the decisions of other federal district courts, this Court finds the reasoning and discussion in *Covert* persuasive.

> Indeed, the *Twombly* Court explained that "something beyond the mere possibility of [a federal violation] must be alleged, lest a plaintiff with a largely groundless claim be allowed to take up the time of a number of other people, with the right to do so representing an *in terrorem* increment of the settlement value." 550 U.S. at 557-58, 127 S.Ct. 1955 (citing *Dura,* 544 U.S. at 347, 125 S.Ct. 1627) (internal quotation marks and punctuation omitted). In that vein, the Court stated that "a district court must retain the power to insist upon some specificity in pleading before allowing a potentially massive factual controversy to proceed [to discovery]." *Id.*

2009 WL 2424559, *10.

The *Covert* court went on to state:

> *As discussed supra, it is apparent that Congress did "clearly and unmistakably" manifest an intent to supersede a large area of state law, including, but not necessarily limited to, any common law duty or positive enactment which "relates to" the labeling, safety and/or effectiveness of the Trident Ceramic System. Indeed, the only recognized exception to express MDA pre-emption that this Court is aware of relates to "parallel" claims; however, as discussed below, Plaintiff's complaint does not sufficiently plead any "parallel" claims.*
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> . . .
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> As discussed above, in order to avoid express pre-emption, Plaintiff must allege a state-law claim which is "genuinely equivalent" to a federal requirement, i.e., one which is premised upon the violation of a federal "requirement." Further, in order to ultimately show an entitlement to relief under any of his "tort" theories of recovery, he must also show that said violation caused his injury. [citation omitted].
>
> Thus, in order to survive the present motion to dismiss, Plaintiff's complaint must put HOC on notice both of the nature of his claims (i.e., that they are "parallel" to federal requirements), as well as the grounds upon which he maintains he is ultimately entitled to relief (i.e., the factual basis for the allegations that his injuries were caused by HOC's violation of an identifiable federal requirement or requirements). Clearly, Plaintiff has adequately put HOC on notice, at least in argument, if not in pleadings, that he believes his claims are "parallel" in nature; however, he has failed to put HOC on notice of the grounds of his purported entitlement to relief in that it is not at all clear whether or how the alleged violations relate to his alleged injuries.

2009 WL 2424559, *14 (emphasis added).

This Court has evaluated the plaintiff's complaint in the instant case and concludes, notwithstanding the finding of the magistrate judge, that plaintiff does not sufficiently plead a

"parallel" claim. Plaintiff's bare-bones allegations merely allege the "redhibitory vices and defects" in the Trident™ System were "peculiarly within the knowledge of the defendant, who manufactured the products but were not disclosed to the petitioner prior to his surgery in 2004" and that plaintiff "would not have agreed to the surgery had he known of the defective products." The foregoing allegations do not sufficiently allege a state law claim which is "genuinely equivalent" to a federal requirement, *i.e.*, one which is premised upon the violation of a federal "requirement," nor do the allegations put Stryker on notice of how violations of a federal requirement relate to the plaintiff's alleged injuries. Simply put, the plaintiff has not sufficiently pled his state law redhibition claim with sufficient factual information or clarity for this Court to determine whether the requirements imposed by Louisiana's redhibition law seek to impose additional or different requirements than those imposed by the FDA. Indeed, nowhere in the plaintiff's complaint does the plaintiff mention the FDA. Considering the foregoing, this Court concludes the plaintiff has not sufficiently pled a "parallel" claim.

Therefore,

IT IS ORDERED that Stryker's motion to dismiss plaintiff's state law claims brought under the Louisiana Products Liability Act is GRANTED, for the reasons set forth in the Magistrate Judge's Report and Recommendation, and the foregoing claims are DISMISSED WITH PREJUDICE.

IT IS FURTHER ORDERED that Stryker's motion to dismiss plaintiff's redhibition claim

is GRANTED, and the foregoing claim is DISMISSED WITH PREJUDICE.

THUS DONE AND SIGNED in Lafayette, Louisiana, this 15 day of March, 2010.

REBECCA F. DOHERTY
UNITED STATES DISTRICT JUDGE